**Sub-study Definition and Guidance for Submission**

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| **Tip #1: What is a sub-study?**   * A sub-study asks a separate research question from the parent protocol, contributes to the parent protocol’s objectives and uses all or a subset of study participants or specimens. * The sub-study may be incorporated into a main/parent protocol OR a separate sub-study protocol may be created and submitted under the same IRB # if the criteria in Tip #2 are met. |
| **Tip #2: When may the addition of a sub-study be considered a Modification or Amendment to the main/parent study?**  The addition of a sub-study may be considered a modification or amendment if all of the following criteria are met:   * Sub-study hypothesis and objectives compliments and are consistent with the aims of the main/parent study   + When the data being collected in the sub-study complements the data collected in the existing parent protocol   + To collect data related to that population’s experience in the study or with the investigational product (e.g., quality of life survey) * The subjects being enrolled in the sub-study are a subset of the subjects enrolled in the main/parent study that is being modified. * The funding source for the sub-study is the exactly the same (same sponsor or same grant) * Enrollment tracking and adverse event reporting may be done under the main/parent protocol. Separate enrollment tracking and adverse event reported are not needed at the UVA IRB Level (see Tip 4 below for additional information) * A database protocol is not being added. A separate database protocol is always required to create a data or tissue repository. |
| **Tip #3: When is a new study submission required?**  **A separate new study is required if all the following criteria are met:**   * Study objectives or outcomes differ from the existing main/parent protocol * Subjects to be enrolled in the sub-study are NOT a subset of the subjects in the main/parent protocol * Funding source for the sub-study is different from the main/parent study. * Separate enrollment tracking and adverse event reporting are needed at the UVA IRB level. (see Tip 4 below for additional information) * Storing samples and/or data for future research (bio-bank protocol) . (A separate database protocol is always required for this) |
| **Tip #4: Which submission is the most appropriate for this sub-study?**   |  |  | | --- | --- | | **Submit the SUB-STUDY- Add to existing protocol as an Amendment or Modification** | **Submit the SUB-STUDY as a new stand-alone study**  **(new IRB #/ UVA Study Tracking# is required)** | | Objectives/hypothesis are consistent with the main/parent study. They need not be identical but serve to expand the original research intent. | Objectives/Hypothesis are broadly different than the main/parent study. | | Subjects enrolled in the sub-study are a subset of those subjects enrolled in the main/parent study | Subjects enrolled in the sub-study are NOT a subset of those subjects enrolled in the main/parent protocol. | | Same funding source/or same grant as the main/parent study | Different funding source or different grant than the main/parent study | | Sub-study does not requires separate tracking at the local IRB level for enrollment and/or adverse event reporting:   * 1. Enrollment totals – will not require separate tracking with the IRB. Enrollment in the sub-study will not be reported as separate from the enrollment in the main/parent protocol at the time of continuing review. (e.g., enrollment numbers will be combined (numbers of those participating in the sub-study are not counted separately from the main/parent study enrollment number),   2. Adverse Events will be reported under the main/parent protocol | Sub-study requires separate tracking at the local IRB level for enrollment and/or adverse event reporting   1. Enrollment totals –require separate tracking with the IRB. Enrollment in the sub-study will be reported as separate from the enrollment in the main/parent protocol at the time of continuing review. (e.g., enrollment numbers will NOT be combined (numbers of those participating in the sub-study are counted separately from the main/parent study enrollment number) 2. Adverse events need to be reported to the IRB-HSR separately from those of the main/parent protocol. | | A DATABASE PROTOCOL is not being added to the main/parent study. A separate DATABASE PROTOCOL submission is always required to store data or specimens after the main/parent study closes. | A DATABASE PROTOCOL is being added to the main/parent study. A separate DATABASE PROTOCOL submission is always required to store data or specimens after the main/parent study closes | |